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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,034	05/29/2001	Roberto A. Macina	DEX-0207	5629

26259 7590 11/06/2002

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MARLTON, NJ 08053

EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,034

Applicant(s)

MACINA ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9,10,11                      6) ☐ Other: \_\_\_\_\_

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

#### **DETAILED ACTION**

This application contains claim drawn to nonelected species with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected species or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Allowable Subject Matter***

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections - 35 USC § 112***

Claim 1 **remain rejected** for the reasons set forth in the prior Office Action pages 3-5 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5, does not reasonably provide enablement for any other CGS, defined as nucleotides molecules that have 95 % identity to SEQ ID NO:5. Applicant argue that the amended claim is enabled now because the claim no longer recites "variant" but this argument is not persuasive because the claim is still drawn to variant of SEQ ID NO:5 now defined as "95 % identity" to SEQ ID NO:5. In light of the teachings of the specification at page 1 lines 19 and 20 as well as page 3 lines 28-30 that says that CSG means polynucleotides which due to degeneracy in genetic coding, comprise variations in nucleotide sequence, the claims are interpreted as drawn to SEQ ID NO:5 and its allelic variants. As stated before in the previous Office Action, the art recognizes that use of a human gene as a cancer marker is unpredictable. Sasaki et al (Biochem Biophys Res Commun 2002 Sep 27, 297/3:558) teach that slight change, i.e., one nucleotide change (over 99 % identity) in a human gene may contribute cancer development. It is highly unpredictable if any allelic variant of SEQ ID NO:5 could be

also used as colon cancer marker and causes undue experimentation to practice the full scope of the claims.

Claim 1 **remains rejected** for the reasons set forth at pages 8 and 9 of the prior Office Action mailed on 5/21/2002 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. Applicant argues that the rejection should be withdrawn because the claim no longer recites "variant". However, the claim is still drawn to genus of CSG (colon specific gene) defined as "95 % identity to SEQ ID NO:5. The specification at page 1 lines 19 and 20 says that CGS is a colon specific gene and at page 3 lines 28-30 says that CSG means polynucleotides which due to degeneracy in genetic coding, comprise variations in nucleotide sequence as compared to SEQ ID NO:5. These definition of CSG indicate that claim 1 is drawn to SEQ ID NO:1 and allelic variants that have 95 % identity to SEQ ID NO:5. As stated in the prior Office Action and reiterated above, the specification provides evidence for only SEQ ID NO:5 that is a CGS. Based on only species, one cannot predict the types of additional species such as an allelic variant. Since the genus includes a large number of unpredictable species, possession of only species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicant adequately describes SEQ ID NO:5.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
October 31, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
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